

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER: GRANDWAY TECHNOLOGY (SHENZHEN) LIMITED
BLOCK 7, ZHU KENG INDUSTRIAL ZONE, PING SHAN DISTRICT, 518118
SHENZHEN, PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: DIGITAL AUTOMATIC BLOOD PRESSURE MONITOR
MD4000

CLASSIFICATION – ANNEX IX: **CLASS IIA, RULE 10**

CONFORMITY ASSESSMENT ROUTE: ANNEX II.3

<THIS DECLARATION OF CONFORMITY IS ISSUED UNDER OUR SOLE RESPONSIBILITY>

WE, GRANDWAY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE
93/42/EEC CONCERNING MEDICAL DEVICES AMENDED ACCORDING TO 2007/42/EC OF THE
EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 SEPTEMBER, 2007

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED – EN) STANDARDS FOR WHICH DOCUMENTED
EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

EN ISO 13485:2012	IEC 60601-1-6:2010+A1:2013	ISO 10993-10:2010
EN 60601-1-2:2007+AC:2010	IEC 60601-1-11:2010	EN ISO 14971:2012
EN 1060-1:1995+A2:2009	IEC 62304:2006	ISO 81060-2:2013
EN 1060-3:1997+A2:2009	IEC 62366:2007	
EN 1060-4:2004	IEC 80601-2-30:2009+A1:2013	
IEC 60601-1:2012	ISO 10993-5:2009	

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTER 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER: **CE** 0123

(EC) CERTIFICATE(S): G1130761379015
DATE OF EXPIRY: 31ST AUG OF 2018

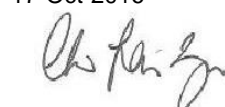


EUROPEAN REPRESENTATIVE: Shanghai International Trading Corp. GmbH (Hamburg)
Eiffestrasse 80, 20537 Hamburg, Germany

START OF CE-MARKING: Feb-2015

PLACE, DATE OF DECLARATION: BLOCK 7, ZHU KENG INDUSTRIAL ZONE, PING SHAN DISTRICT, 518118
SHENZHEN, PEOPLE'S REPUBLIC OF CHINA
17-Oct-2016

SIGNATURE:



NAME: PATRICK CHOW
POSITION: GENERAL MANAGER

